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| 09/040,485 | 03/17/98 | RADOSEVICH | J [illegible]/3 |

EXAMINER

HM22/0604

BRINKS HOFER GILSON AND LIONE
NBC TOWER
SUITE 3600
POST OFFICE BOX 10395
CHICAGO IL 60610

| ART UNIT | PAPER NUMBER |
|---|---|
| WORRALL, T | 10 |

DATE MAILED: 06/04/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 04/19/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 1-18 is/are pending in the application.
Of the above, claim(s) 1-5, 8, and 12-18 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 6, 7, and 9-11 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
☐ ~~Interview Summary, PTO-413~~
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**–SEE OFFICE ACTION ON THE FOLLOWING PAGES–**

## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election without traverse of Group II, claims 6, 7, 9-11, and 17-18 in Paper No. 9 is acknowledged.

2. Upon further consideration, additional restriction is required.

3. Claims 17 and 18 are drawn to an isolated genomic DNA molecule and a vector comprising isolated cDNA. Claims 17 and 18 are therefore regrouped with the claims of Group I. All claim groupings are listed below.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 17-18 are drawn to polynucleotide sequences, classified in class 536, subclass 23.1.

II. Claims 6, 7, 9-11 drawn to proteins and peptides, classified in class 530, subclass 350+.

III. Claims 12-14, drawn to an antibody, classified in class 530, subclass 387.1+.

IV. Claim 8 and 15, drawn to detection methods using DNA hybridization probes, classified in class 435, subclass 6.

V. Claim 16, drawn to attenuating the expression of a cDNA molecule, classified in class 536, subclass 24.5.

5. The inventions are distinct, each from the other because of the following reasons:

6. The proteins compositions of Group I, claims 6, 7, and 9-11, are related to the nucleic acids of Group II, claims 1-5 and 17-18 since the polynucleotides encode the protein compositions. Although they are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from non-recombinant cells. Further, the DNA may be used for processes other than the production of the protein, such as a nucleic acid

hybridization assay. The examination of both groups would require different searches in the U.S. Patent Shoes and the scientific literature, and would require the consideration of different patentability issues.

7. During a telephone conversation with Alice O. Martin on May 26, 1999, a provisional election was made without traverse to prosecute the invention of Group II, claims 6, 7, and 9-11. Affirmation of this election must be made by applicant in replying to this Office action.

8. Claims 1-5, 8, and 12-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

9. CLAIMS 1-18 ARE PENDING.

CLAIMS 6, 7, AND 9-11 ARE EXAMINED ON THE MERITS.

***Drawings***

10. The drawings are objected to. Please see the attached Notice of Draftperson's Patent Drawing Review. Correction is required. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

***Claim Rejections - 35 USC § 101***

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 6, 7, 9, 10, and 11 are rejected under because the claimed invention is directed to non-statutory subject matter.

The claims, as broadly written, embrace the naturally occurring protein and peptide products found in nature. The claims read on the intact organism from which they were isolated. Therefore, the claims must be limited such that they do not encompass the natural product.

Amending the claims to recite "an isolated and purified amino acid molecule consisting of the sequence" would obviate this rejection.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to "cDNA segments." It is unclear whether Applicant means a segment of the cDNAs, or the full length cDNAs. In addition, there is no antecedent basis for the term "segments."

15. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6 and 7 recite the limitations "claim 1" and "claim 2," respectively. There is insufficient antecedent basis for this limitation in the claim, as claims 1 and 2 are drawn to non-elected inventions.

16. Claims 6, 7, 9, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite for reciting "amino acid sequence," as it is not clear whether applicant wishes to claim the "sequence" or the product amino acid comprising (or consisting of) the sequences. A claim to a "sequence" claims the information describing the amino acids, whereas claim to "amino acid sequences" claim the composition. Information is not a chemical structure. Therefore, it is not clear how "sequences" can be claimed in a product claim. Replacing this term with "amino acid molecule" or "polypeptide," as appropriate, would obviate this rejection.

17. Claims 6, 7, 9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The claims are drawn to amino acid sequences that are not identified by a SEQ ID NO. Specifically, claims 6, 7, and 9 are drawn to sequences identified by FIG. 1 or FIG. 2, and claim 11 is identified an amino acid sequence PTGEPQ.

37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the claims of the invention. Accordingly, the amino acid sequences encoded by the polynucleotides claimed by figure number or by single-letter amino acid designations must instead be claimed by using the SEQ ID NO corresponding to the claimed sequence.

18. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim depends from non-elected claim 2, which is drawn to a polynucleotide with 70% homology to a claimed polynucleotide sequence.

It is not clear what is meant by the word "homology." The term "% homology" does not provide a standard for ascertaining the requisite degree of sequence similarity, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The specification does not refer to either an algorithm or the parameters used in conjunction with the algorithm necessary to define sequences with specific sequence homology. Further, despite the high level of skill in the genetic analysis art, there remains a lack of development concerning the definition of the word "homology," as evidenced by Lewin (Science 237:1570 (1987)), in which homology is defined as "the inference of common evolutionary origin (page 1570, final paragraph)." In addition, as further evidenced by Reeck et al (Cell 50:667 (1987)), homology has a precise meaning in biology of having a common evolutionary origin between two or more things. Thus homology is a concept of quality; amino acid or nucleic acid sequences are either homologous or they are not. Thus it is not clear what is meant by the phrase "70% homology."

19. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to "a molecule having an amino acid sequence" and "fragments."

A "molecule having an amino acid sequence" and "fragments" includes proteins and peptides that have peptide backbones and side-chains, as well as protein-nucleic acid hybrid molecules, that have nucleic acid backbones and amino acid side chains.

Deleting the phrase "a molecule having" and replacing it with "a molecule comprising of" or "a molecule consisting of" (as appropriate) would obviate this rejection.

20. Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to sequences that are defined by single letter designations (e.g. APPEDNPVED) for each amino acid.

37CFR 1.821-1.825 state that amino acid sequences must be claimed and disclosed by using 3 letter designations well known in the art. Further, only the specific SEQ ID NO designations are necessary in order to claim the sequence.

Defining all claimed sequences in terms of only their SEQ ID NO designations would obviate this rejection.

21. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a molecule "having" a specific amino acid sequence.

The term "having" is defined as "to have in whole or in part." It is therefore unclear whether applicant is claiming a sequence defined by a specific SEQ ID NO or a fragment of that sequence.

Replacing the term "having" with "comprising" in instances where the term "having" is used to define a sequence would obviate this rejection.

22. Claim 9 is indefinite as being structured as an improper Markush claim, by reciting the format "consisting of the group A, B, C, D, and E or F." Proper Markush claims are in the following format: "X is selected from a group consisting of A, B, C, and D" or "the X is A, B, C or D." (See MPEP 2173.05 (h)).

***Claim Rejections - 35 USC § 102***

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Hodges et al (US Patent 5,223,604). The claim is drawn to a vaccine comprising a fragment of the peptides defined by SEQ ID NOS:6, 7, 8, or 9.

Given its broadest possible scope, a fragment of the claimed sequence comprises a single amino acid. Proline comprises a fragment of the claimed sequences. Hodges et al teach a vaccine comprising a peptide (SEQ ID NO:2 in Hodges et al) containing a proline residue. Therefore, Hodges et al teaches a vaccine comprising a fragment of the claimed sequences.

25. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Korioth et al (Gene 150:395-399 (1994)). The claim is drawn to an amino acid sequence comprising SEQ ID NO:6 or SEQ ID NO:8.

Korioth et al teach an amino acid sequence comprising SEQ ID NO:6 (page 396, Figure 1, amino acids 281-290) and SEQ ID NO:8 (page 396, Figure 1, amino acids 173-182).

26. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Jia et al (J. Biol. Chem. 267:14322-14327 (1992)). The claim is drawn to an amino acid sequence comprising SEQ ID NO:9.

Jia et al teach an amino acid sequence comprising SEQ ID NO:9 (page 14324, Figure 2, amino acids 248-257).

27. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Korioth et al (Gene 150:395-399 (1994)). The claim is drawn to an amino acid sequence comprising amino acids 3-8 of SEQ ID NO:8.

Korioth et al teach an amino acid sequence comprising amino acids 3-8 of SEQ ID NO:8 (page 396, Figure 1).

***Conclusion***

28. CLAIMS 6 AND 7 ARE FREE OF THE PRIOR ART.

29. NO CLAIM IS ALLOWED.

30. Any inquiry concerning the communication or earlier communications from the examiner should be directed to Timothy A. Worrall, Ph.D. whose telephone number is (703) 308-9348. The examiner can normally be reached on Monday through Friday from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014.

Communications via Internet-e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements under 35 8U.S.C.122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997, at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Timothy A. Worrall, Ph.D.

May 1, 1999

JULIE BURKE
PRIMARY EXAMINER